



# Knoxville Vapor LLC 4/2/15

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Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Center for Tobacco Products  
10903 New Hampshire  
Avenue  
Silver Spring, MD 20993

**APR 2, 2015**

**VIA UPS and Electronic Mail**

Teresa Livezey  
Knoxville Vapor  
5201 Kingston Pike Unit #4  
Knoxville TN 37919  
knoxvillevapor@gmail.com

**WARNING LETTER**

Dear Ms. Livezey:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed your website, <http://knoxvillevaporshop.com>, and determined that you sell or distribute e-liquids that contain nicotine to consumers in the United States. Specifically, your website advertises e-liquids that contain varying amounts of nicotine (e.g., 3mg, 8mg, 18mg or 24mg). Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act

(Tobacco Control Act), these products are tobacco products because they are made or derived from tobacco and intended for human consumption.

### **Section 301(tt) Violation**<sup>[1]</sup>

FDA has determined that a statement made on the website, <http://knoxvillevaporshop.com>, regarding your e-liquids violate section 301(tt) of the FD&C Act (21 U.S.C. 331(tt)) which prohibits, in pertinent part:

“(m)aking any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that”

- (1) the product is approved by the Food and Drug Administration;
- (2) the Food and Drug Administration deems the product to be safe for use by consumers;
- (3) the product is endorsed by the Food and Drug Administration for use by consumers; or
- (4) the product is safe or less harmful by virtue of<sup>1</sup>
  - (A) its regulation or inspection by the Food and Drug Administration; or
  - (B) its compliance with regulatory requirements set by the Food and Drug Administration<sup>2</sup>

Specifically, your website advertises the following e-liquids that are sold or distributed in varying amounts of nicotine (e.g., 3mg, 8mg, 18mg or 24mg), including but not limited to: 555, Absolute Pin (30mL), Ambrosia, American Tobacco, Apple Brandy (15mL), Apple Pie Moonshine (15mL) and Appletini. These products are sold or distributed on your website, which includes the statement that your e-liquids are, “tested, created and bottled in an FDA and/or AEMSA certified lab.”

Because this statement on your website is directed toward consumers and conveys, or would mislead consumers into believing, that the above-listed tobacco products are endorsed by the FDA or that the products are safe or less harmful by virtue of regulation by FDA, they are in violation of section 301(tt) of the FD&C Act.

### **Conclusion and Requested Actions**

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with the applicable provisions of the FD&C Act.

It is your responsibility to ensure that your tobacco products and all related promotional materials on this website, on any other websites (including e-commerce, social networking, or search engine websites), in any other media in which you advertise, and in retail establishment(s) comply with each applicable provision of the FD&C Act and FDA’s implementing regulations. Failure to ensure full compliance with the applicable provisions of the FD&C Act may result in FDA initiating further action without notice, including, but not limited to, civil money penalties, criminal prosecution, and/or injunction.

Please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative promotion, advertising, sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act.

Please note your reference number, RW1500287, in your response and direct your response to the following address:

DPAL-WL Response, Office of Compliance and Enforcement  
FDA Center for Tobacco Products  
c/o Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact Ele Ibarra-Pratt at (301) 796-9235 or via email at [CTPCompliance@fda.hhs.gov](mailto:CTPCompliance@fda.hhs.gov).

Sincerely,

/S/

Ann Simoneau, J.D.  
Director  
Office of Compliance and Enforcement  
Center for Tobacco Products

**VIA Electronic Mail**

cc:

DotBlock.com  
<http://abuse@dotblock.com>

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[1] Certain tobacco products, including e-liquids that contain nicotine, are not yet deemed subject to the tobacco product authorities under Chapter IX of the FD&C Act. However, because your products meet the definition of a tobacco product, they must comply with applicable provisions that are outside of Chapter IX of the FD&C Act, including section 301(tt) of the FD&C Act.



# Dr. K 4/2/15

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Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Center for Tobacco Products  
10903 New Hampshire  
Avenue  
Silver Spring, MD 20993

**APR 2, 2015**

**VIA UPS and Electronic Mail**

Dr. K  
Attn: Sue J Hyung  
1955 Raymond Dr. Ste. 106  
Northbrook, IL 60062  
drkeliquid@hotmail.com

**WARNING LETTER**

Dear Ms. Hyung:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed your website, <http://www.drkeliquid.com>, and determined that you sell or distribute e-liquids that contain nicotine to consumers in the United States. Specifically, your website advertises e-liquids that contain varying amounts of

nicotine (e.g., 0.8%, 1.6%, or 2.4%). Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), these products are considered tobacco products because they are made or derived from tobacco and are intended for human consumption.

### **Section 301(tt) Violation**<sup>[1]</sup>

FDA has determined that the statements or representations made on the website <http://www.drkeliqoid.com> regarding your e-liquids violate section 301(tt) of the FD&C Act (21 U.S.C. 331(tt)), which prohibits, in pertinent part:

making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

1. the product is approved by the Food and Drug Administration;
2. the Food and Drug Administration deems the product to be safe for use by consumers;
3. the product is endorsed by the Food and Drug Administration for use by consumers; or
4. the product is safe or less harmful by virtue of
  - A. its regulation or inspection by the Food and Drug Administration; or
  - B. its compliance with regulatory requirements set by the Food and Drug Administration.

Specifically, your website advertises the following e-liquids that are sold or distributed in varying amounts of nicotine (e.g., 0.8%, 1.6% or 2.4%), including, but not limited to: Apple (15 ML), Banana (15 ML), Blackberry (15 ML), Blueberry (15 ML), Cherry (15 ML), Grape (15 ML), Ice Mint (15 ML), Kiwi (15 ML), Lemon (15 ML), and Mango (15 ML). These products are sold or distributed on your website, which includes the following statements: "FDA Registered Lab" and "Formulas FDA Registered."

Because these statements on your website are directed to consumers and convey, or would mislead consumers into believing, that the above-listed tobacco products are endorsed by the FDA or that the products are safe or less harmful by virtue of regulation by FDA, they are in violation of section 301(tt) of the FD&C Act.

In addition, it has come to our attention that one of the retail outlets appears to be selling your e-liquids from a display case marked with your firm's name and the claim "FDA approved," which conveys or would mislead consumers into believing that your products are approved by FDA.

### **Conclusion and Requested Actions**

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with the applicable provisions of the FD&C Act.

It is your responsibility to ensure that your tobacco products and all related promotional materials on this website, on

any other websites (including e-commerce, social networking, or search engine websites), and in any other media in which you advertise and in retail establishment(s) comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to ensure full compliance with the applicable provisions of the FD&C Act may result in FDA initiating further action without notice, including, but not limited to, civil money penalties, criminal prosecution, and/or injunction.

Please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative promotion, advertising, sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act.

Please note your reference number, RW1500260, in your response and direct your response to the following address:

DPAL-WL Response, Office of Compliance and Enforcement  
FDA Center for Tobacco Products  
c/o Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact Ele Ibarra-Pratt at (301) 796-9235 or via email at [CTPCCompliance@fda.hhs.gov](mailto:CTPCCompliance@fda.hhs.gov).

Sincerely,

/S/

Ann Simoneau, J.D.

Director

Office of Compliance and Enforcement

Center for Tobacco Products

**VIA Electronic Mail**

cc:

ENOM, Inc.

abuse@enom.com

Bigcommerce, Inc.

abuse@bigcommerce.com

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[1] There are certain tobacco products, including e-liquids that contain nicotine, which are not currently subject to the tobacco product authorities under Chapter IX of the FD&C Act. However, because e-liquids meet the definition of a tobacco product, such products must comply with applicable provisions that are outside of Chapter IX of the FD&C Act, such as, section 301(tt) of the FD&C Act.

### Close Out Letter

- [Dr. K - Close Out Letter 7/1/15](#)

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# www.vaperz.co.uk 4/2/15

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Department of Health and Human Services

Food and Drug Administration  
Center for Tobacco Products  
10903 New Hampshire  
Avenue  
Silver Spring, MD 20993

**APR 2, 2015**

**VIA Electronic Mail**

Ms. Claire Riddington-Smith, Director  
Vaperz Ltd.  
claire@vaperz.co.uk

**WARNING LETTER**

Dear Ms. Riddington-Smith:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed your website, <http://www.vaperz.co.uk>, and determined that you sell or distribute electronic cigarettes and e-liquids that contain nicotine to customers in the United States. Specifically, your website advertises electronic cigarettes and e-liquids that contain nicotine in the amount of 16mg or 24mg. Under section 201(rr) of the Federal Food, Drug, and

Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), these products are tobacco products because they are made or derived from tobacco and intended for human consumption.

### **Section 301(tt) Violation[1]**

FDA has determined that the statements or representations made on the website, <http://www.vaperz.co.uk>, regarding your electronic cigarettes and e-liquids violate section 301(tt) of the FD&C Act (21 U.S.C. 331(tt)) which prohibits, in pertinent part:

Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

- (1) the product is approved by the Food and Drug Administration;
- (2) the Food and Drug Administration deems the product to be safe for use by consumers;
- (3) the product is endorsed by the Food and Drug Administration for use by consumers; or
- (4) the product is safe or less harmful by virtue of
  - (A) its regulation or inspection by the Food and Drug Administration; or
  - (B) its compliance with regulatory requirements set by the Food and Drug Administration

Specifically, your website advertises electronic cigarettes and the following flavored e-liquids that are sold or distributed to U.S. customers, which contain nicotine in the amount of 16mg and/or 24mg, including but not limited to: Juicy Peach, Almond, Cinnamon, American Blend and Watermelon. These products are sold or distributed on your website, which displays imaged copies of various certificates purported to be from different organizations under the tab "Certificates," including a graphic image of the "Certificate of FDA Registration," titled "FDA-Approval.jpg."

Because these statements or representations on your website are directed to consumers and convey, mislead, or would mislead consumers into believing, that the above-listed tobacco products are approved by the FDA, they are in violation of section 301(tt) of the FD&C Act.

### **Conclusion and Requested Actions**

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with applicable provisions of the FD&C Act.

It is your responsibility to ensure that your tobacco products and all related promotional materials on this website, on any other websites (including e-commerce, social networking, or search engine websites), and in any other media in which you advertise comply with each applicable provision of the FD&C Act and FDA's implementing regulations.

Failure to ensure full compliance with applicable provisions of the FD&C Act may result in FDA initiating further action without notice, including, but not limited to, civil money penalties, criminal prosecution, and/or injunction.

Please submit a written response to this letter within 15 working days from the date of receipt

describing your corrective actions, including the dates on which you discontinued the violative promotion, advertising, sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act.

Please note your reference number, RW1500288, in your response and direct your response to the following address:

DPAL-WL Response, Office of Compliance and Enforcement  
FDA Center for Tobacco Products  
c/o Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact Ele Ibarra-Pratt at (301) 796-9235 or via email at [CTPCompliance@fda.hhs.gov](mailto:CTPCompliance@fda.hhs.gov).

Sincerely,

/S/

Ann Simoneau, J.D.

Director

Office of Compliance and Enforcement

Center for Tobacco Products

#### **VIA Electronic Mail**

cc:

abuse@cloudflare.com

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[1] Certain tobacco products, including e-liquids that contain nicotine, are not yet deemed subject to the tobacco product authorities under Chapter IX of the FD&C Act. However, because your products meet the definition of a tobacco product, they must comply with applicable provisions that are outside of Chapter IX of the FD&C Act, including section 301(tt) of the FD&C Act.

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### Compliance Actions and Activities

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### Gamucci 9/8/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Silver Spring, MD 20993-0002

#### WARNING LETTER

September 8, 2010

Ms. Shena Malave  
President  
Gamucci America  
c/o Smokey Bayou, Inc.  
9838 Old Bay Meadows Road, Suite 332  
Jacksonville, Florida 32256

Dear Ms. Malave:

This letter concerns products marketed by your firm under the "Gamucci" name, including the components thereof. According to your Internet website, [www.gamucci-america.com](http://www.gamucci-america.com), Gamucci America is an authorized distributor of Gamucci Electronic Cigarettes and Cigars and is owned and operated by Smokey Bayou Inc.

Based on our review of the labeling for the "Gamucci products," which includes your Internet website ([www.gamucci-america.com](http://www.gamucci-america.com)), these products include two different forms of electronic smoking products: one product that mimics conventional cigarettes, and one that mimics conventional cigars. These products are often called "electronic cigarettes," "e-cigarettes," and "e-cigars." The Gamucci products are constructed with a rechargeable battery, a microprocessor, a heating element, an atomizer, and a replaceable cartridge that contains certain chemicals, including nicotine (in varying specified levels). You also distribute the cartridge refill packs in various flavors such as cherry, coffee, peach, menthol, and apple that are available in different nicotine strengths. Nicotine and/or other chemicals are intended to be volatilized when the user inhales through these electronic cigarette products. These electronic products do not contain tobacco leaf or stem. Each product is intended to heat air as it is drawn through it by the user. This heated air purportedly volatilizes the chemicals contained in the replaceable cartridge component of these products. The volatilized chemicals are then inhaled by the user.

According to your website, these products are based on "a very sophisticated micro-electronic technology which provides a non flammable smoking experience" and that the nicotine and/or other chemicals ("less than 20 chemicals . . . including mostly nicotine [and] propylene glycol") that are volatilized and inhaled from these products "can cause stimulation, a feeling of relaxation, calmness, and alertness [which] . . . can last from minutes to hours." Your website explains that "[these products] provide all [the] same pleasures [the nicotine, emotional and physical sensations], but without all the problems commonly associated with traditional smoking."

Your website offers these products as an aid to help smokers quit smoking:

- "use the device to cut down, break the habit and ultimately quit smoking altogether . . .
- [o]ther quit smoking methods have little success with many smokers, so it is not surprising [sic] that people who are trying to quit will try his too . . .

• [a]nd given the reports, it seems to be working for many.”

As presently labeled and promoted, these Gamucci products violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). As described in more detail below, Gamucci products are unapproved new drugs marketed in the United States in violation of section 505 of the Act (21 U.S.C. § 355) and are misbranded under section 502 of the Act (21 U.S.C. § 352).

Both the “drug” and “device” definitions in sections 201(g) and 201(h) of the Act (21 U.S.C. §§ 321(g) and (h)), encompass products intended either to affect the structure or function of the body or to cure, mitigate, treat, or prevent disease. Based on our review of the Gamucci products and their associated labeling and promotional materials, these products are drug-device combination products, with a drug primary mode of action.

Statements in labeling and promotional materials, including your Internet website at [www.gamucci-america.com](http://www.gamucci-america.com), that reflect the intended uses for the products you market, include, but are not limited to, the following:

“Home . . .

“You won’t have to worry about smoking tobacco, tar or the other 4000 carcinogenic traditional cigarettes have. E-Cigarettes look, feel, and taste like traditional cigarettes, yet they are far from it. They are a healthier alternative to smoking.”

“The Gamucci Electronic Cigarettes do not produce smoke, but rather a harmless water vapor. In addition to this there are no dangers of passive smoking.”

“FAQ . . .

Are Electronic Cigarettes safe?

Clinical trials have now been carried out in New Zealand by Dr Murray Laugeson of Health New Zealand that prove that Electronic Cigarettes are very safe. Please click on Report by Health New Zealand to view in full . . .”

“Media . . .

**TobaccoHarmReduction.org**

[T]he leading source of information of safer alternatives for smokers who cannot or do not wish to quit using nicotine.

**Electronic Cigarettes . . .**

**Are they really safer than regular cigarettes? -Yes.**

**Are they as safe as using smokeless tobacco? -Maybe.**

**Could these help me quit all nicotine use? -Maybe.**

They might. Switching away from smoking is the most important thing to do so even if you end up not quitting. At least it won't harm you the way smoking will. Some people have found that electronic cigarettes reduce their need to smoke somewhat. E-cigarette Direct has posted a collection of e-cig user comments [<http://www.e-cigarettedirect.co.uk/research/comments.html>] about their experiences with many reporting that they have reduced or quit traditional smoking. The products are available with varying levels of nicotine, from a lot to none, so they can be used as a weaning product.

It does not strictly qualify as scientific evidence but indications are that e-cigarettes are being used successfully by many to quit smoking, with many of the quitters having a history of trying other methods and failing . . . Every anecdote so far appears to tell the same story; a cigarette smoker is switching over, sometimes just part time but more often full time, to this safer alternative.

Other quit smoking methods have little success with many smokers, so it is not surprising [sic] that people who are trying to quit will try this too. And given the reports, it seems to be working for many. In time we should see some formal studies but in the meanwhile, on a person to person basis, some smokers are rapidly reducing their health risks . . .

**Electronic Cigarette News**

Discover the E Cigarette And Stop Smoking Aid . . .

**Electronic Cigarettes – Stop Smoking Aid Or Cigarette Substitute? . . .**

July 2nd, 2009 . . . I think the electronic cigarette is a great stop smoking aid and definitely the best nicotine replacement therapy available on the market but should we really be treating them as a long term substitute for smoking or a stepping stone to a drug free existence? I used the e cigarette along

with the "easy way to stop smoking" book by Allen Carr to rid myself of nicotine and wholeheartedly recommend them to any smoker who wants to quit. But, my belief is that our aim should be to work on becoming nicotine free as possible.

Don't get me wrong, swapping tobacco for vaporized nicotine is going to do wonders for your health if you are a long term smoker but cutting out nicotine entirely should be the next step . . .

There's no doubt in my mind that E Cigarettes are miles ahead of tobacco products as a way to deliver nicotine to the system in terms of their effect on your health but is your aim to find a healthier way to be a drug addict or to free yourself from the shackles of addiction for good?

My advice is to get a hold of the "Easy way to stop smoking" book and an E cigarette if you need it as a way to get off the smokes. In time wean yourself off nicotine altogether and you'll find life to be an altogether more enjoyable experience."

#### **Nicotine Replacement Therapy Causes Cancer**

April 22nd, 2009 . . . using an E Cigarette for a few months as a stepping stone to becoming nicotine free is infinitely preferable to continuing to smoke and is currently the best way to quit smoking we have."

The above statements demonstrate that the Gamucci products marketed by your firm are intended both to affect the structure or function of the body and to mitigate, treat, or prevent disease. See 21 C.F.R. § 201.128 (describing the meaning of "intended use"). In particular, these statements suggest that these products are intended for use as smoking deterrents or to reduce dependence on traditional tobacco products, and are also capable of delivering nicotine. The scientific and medical communities have determined that nicotine is a pharmacological agent,<sup>1</sup> that nicotine addiction is a disease,<sup>2</sup> and that nicotine withdrawal is itself a recognized medical condition.<sup>3</sup> It is well understood that people smoke for the pharmacologically rewarding effects of nicotine, such as alleviation of stress and negative mood, enhancement of thinking, and increased alertness.<sup>4</sup> For an addicted smoker, the body has adapted to nicotine, and abstinence produces withdrawal and craving.<sup>5</sup> As a result, people also smoke to avoid the negative effects of nicotine withdrawal, such as anxiety, difficulty concentrating, negative mood, increased appetite, insomnia and irritability.<sup>6</sup> Therefore, the claims noted above demonstrate that the Gamucci products are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease.

As described in 21 C.F.R. § 310.544, any product that bears labeling claims that it "helps stop or reduce the cigarette urge," "helps stop or reduce smoking," or similar claims is a smoking deterrent drug product.<sup>7</sup> Products that are labeled, represented, or promoted as smoking deterrents, such as the Gamucci products marketed by your firm, are regarded as "new drugs" under section 201(p) of the Act (21 U.S.C. § 321(p)) because there is a lack of adequate data establishing that they are generally recognized as safe and effective for such use. See 21 C.F.R. § 310.544. These products are also "new drugs" under the Act because we are not aware of any data establishing that these Gamucci products are generally recognized among scientific experts as safe and effective for the other drug uses described above and in the products' labeling. "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. § 355) to be legally marketed in the United States. None of the Gamucci products or any of their components marketed by your firm is so approved; therefore, marketing these products in the United States violates section 505 of the Act.

The Gamucci products marketed by your firm are also misbranded under section 502 of the Act (21 U.S.C. § 352) because they are intended for use as smoking deterrents under 21 C.F.R. § 310.544 but are not covered by an approved new drug application. The Gamucci products are further misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)) because they do not bear adequate directions for their intended drug uses, including smoking deterrence. "Adequate directions for use" is defined in 21 C.F.R. § 201.5 as "directions under which the layman can use a drug safely and for the purposes for which it is intended."

Please be aware that the FDA has issued a letter addressed to the Electronic Cigarette Association (ECA) which explains, in detail, how the electronic cigarette industry can begin the drug approval process. For your convenience, we have enclosed a copy of that letter and encourage you to follow through with the recommendations.

The violations cited in this letter are not intended to be an all-inclusive list of deficiencies regarding your products, nor are the arguments raised here regarding them exhaustive. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the referenced violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please state what actions you will take to address products that you have already distributed. If another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Please direct your response to FDA's

Electronic Cigarette Mailbox at [FDAAElectronicCigaretteMailboxCDER@fda.hhs.gov](mailto:FDAAElectronicCigaretteMailboxCDER@fda.hhs.gov) or (301) 796-3110.

Sincerely,  
/Michael M. Levy, Jr./  
Michael M. Levy, Jr., Esq.  
Director, Division of New Drugs and Labeling Compliance  
Office of Compliance  
Center for Drug Evaluation and Research

<sup>1</sup> E.g., P. Taylor, *Agents Acting at the Neuromuscular Junction and Autonomic Ganglia*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 193, 193-218 (J.G. Hardman, L.E. Limbird & A.G. Gilman eds., 2001).

<sup>2</sup> WORLD HEALTH ORGANIZATION, ICD-10 INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES, 10TH REVISION (2nd ed. 2007).

<sup>3</sup> AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL -- TEXT REVISION 192 (2000).

<sup>4</sup> E.g., N.L. Benowitz, *Drug Therapy. Pharmacologic Aspects of Cigarette Smoking and Nicotine*, 319 NEW ENG. J. MED. 1318 (1988).

<sup>5</sup> See WORLD HEALTH ORGANIZATION, *supra* note 2.

<sup>6</sup> E.g. T.B. Baker, T.H. Brandon & L. Chassin, *Motivational Influences on Cigarette Smoking*, 55 ANN. REV. PSYCHOL. 463 (2004).

<sup>7</sup> We note that the determination as to whether e-cigarette products would be considered Rx or OTC will be made during the review of an NDA submission.

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### Ruyan America, Inc. 9/8/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Silver Spring, MD 20993-0002

#### WARNING LETTER

September 8, 2010

Mr. William P. Bartkowski  
President  
Ruyan America, Inc.  
5550 Nicollet Avenue  
Minneapolis, MN 55419

Dear Mr. Bartkowski:

This letter concerns the RUYAN brand of products marketed by your firm, Ruyan America, Inc. (Ruyan America), your joint venture partner Ruyan Holdings Ltd. of Hong Kong, and Nathan & James Group LLC, with which you have a distribution agreement to sell your products in the United States.

Based on our review of the products' labeling and promotional materials, including the Internet websites [www.ruyanamerica.com](http://www.ruyanamerica.com), [www.getruyanusa.com](http://www.getruyanusa.com), and [www.ruyan.com.cn](http://www.ruyan.com.cn),<sup>1</sup> RUYAN products include six different forms of electronic smoking products: two that mimic conventional cigarettes (identified as RUYAN V-8 and RUYAN RAPP E-Mystick), two that mimic conventional cigars (identified as RUYAN Vegas and RUYAN e-Gar), and two that mimic conventional tobacco pipes (identified as Rosewood E-Pipe and Agate E-Pipe) (collectively "RUYAN products"). According to the labeling and promotional materials, these products are "sophisticated electronic devices that use modern microelectronic technology" and "consist of a stainless steel shell, various lithium battery components, [a] microcomputer circuit, a vaporization chamber and a . . . cartridge." Furthermore, "drawing on [ these devices] will produce a water-like vapor" that "allow[s] smokers to satisfy their cravings" to, among other uses, "ratchet down nicotine consumption." The RUYAN products do not contain tobacco leaf or stem.

The RUYAN RAPP E-Mystick is similar in design and function to the other RUYAN products, but instead of containing nicotine, it "contains the active ingredient lobelia . . . an herbal remedy/dietary supplement." RUYAN RAPP E-Mystick is "marketed exclusively to smoking adults as a tonic" whereby "[t]he product provides smokers quick and effective relief for a number of conditions commonly attributed to tobacco use." The RUYAN products are offered, among other things, as aids to deter or cease smoking when one cannot or chooses not to smoke conventional tobacco products.

As presently labeled and promoted, these RUYAN products and their components violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). As described in more detail below, these RUYAN products are unapproved new drugs marketed in the United States in violation of section 505 of the Act (21 U.S.C. § 355) and are misbranded under section 502 of the Act (21 U.S.C. § 352).

Both the "drug" and "device" definitions in sections 201(g) and 201(h) of the Act (21 U.S.C. §§ 321(g) and (h)) encompass products intended either to affect the structure or function of the body or to cure, mitigate, treat, or prevent disease. Based on our review of the RUYAN products and their components marketed by your firm, as

well as their associated labeling and promotional materials, these products are drug/device combination products, with the primary mode of action being that of a drug. Statements in labeling and promotional materials that further reflect the intended uses for these RUYAN products include, but are not limited to, the following:

#### All RUYAN products

[www.ruyan.com.cn](http://www.ruyan.com.cn):

"[RUYAN products] could be used to ratchet down nicotine consumption."

"Ruyan America Inc. of Minneapolis is distributing electronic cigarettes, cigars and pipes that . . . satisfy a smoker's nicotine craving."

Customer Feedback from "kate":

"RUYAN decreases my daily cigarette usage. I mainly use it at home, it helps me reduce 4 - 8 cigarettes per day."

Customer Feedback from "Wu Jiesi":

"I started smoking when I was sixteen years old and I am fifty four now, so I have smoked for 38 years. I have attempted to stop smoking for many times, but failed. I am very anxious about my health. Fortunately, the appearance of 'RUYAN' solves my problem."

Customer Feedback from "Mr. Cui":

"My grandmother smoked like a chimney. After I bought her the Ruyan products, she reduced her cigarette smoking remarkably."

[www.getruyanusa.com](http://www.getruyanusa.com) (as of November 24, 2009):

"Ruyan smoking substitutes use liquids that can contain nicotine . . ." Each product "gives the user the sensation of smoking, without producing the harmful tar, carbon monoxide and other chemicals found in the second hand smoke of traditional tobacco products."

"When using these products, drawing on them will produce a water-like vapor that smokers find satisfying. . . . [T]he products provide the physiological and psychological effects that many smokers require for a satisfying experience."

#### User manual for RUYAN V-8 electronic cigarettes

"Who Should Use This Product . . . Smokers over the age of twenty-one who wish to satisfy their craving and need for nicotine . . ."

"The REC [RUYAN Electronic Cigarette] Device's cartridge contains nicotine. Nicotine is a natural alkaloid substance extracted from the tobacco leaf and certain other plants. It is the substance that causes smokers to become addicted."

"The REC Device is a kind of non-flammable electronic cigarette with efficacies similar to those of the common cigarette. It has been demonstrated to refresh and satisfy smokers . . ."

#### User manual for RUYAN e-GAR electronic cigars

"The cartridge in the RUYAN e-Gar contains nicotine . . . the substance that causes smokers to become addicted."

"Who Should Use This Product: Smokers over the age of twenty-one who wish to satisfy their craving and need for nicotine . . ."

#### Rapp E-Mystick

[www.ruyanamerica.com](http://www.ruyanamerica.com):

"The RAPP E-Mystick is designed for adult smokers who want the look, feel and experience of a cigarette."

"[T]he Ruyan E-Mystick . . . contain[s] the recognized herbal remedy and dietary supplement lobelia and [is] marketed exclusively to smoking adults as a tonic. The product provides smokers quick and effective relief for a number of conditions commonly attributed to tobacco use."

The above statements demonstrate that the electronic cigarette and cigar products marketed by your firm are intended both to affect the structure or function of the body and to mitigate, treat, or prevent disease. See 21 C.F.R. § 201.128 (describing the meaning of "intended use"). In particular, these statements suggest that these products are intended for use as smoking deterrents or to reduce dependence on traditional tobacco products,

and are also capable pharmacological agent,<sup>2</sup> that nicotine addiction is a disease,<sup>3</sup> and that nicotine withdrawal is itself a recognized medical condition.<sup>4</sup> It is well understood that people smoke for the pharmacologically rewarding effects of nicotine, such as alleviation of stress and negative mood, enhancement of thinking, and increased alertness.<sup>5</sup> For an addicted smoker, the body has adapted to nicotine, and abstinence produces withdrawal and craving.<sup>6</sup> As a result, people also smoke to avoid the negative effects of nicotine withdrawal, such as anxiety, difficulty concentrating, negative mood, increased appetite, insomnia and irritability.<sup>7</sup> Therefore, the statements noted above demonstrate that the electronic cigarette and cigar products marketed by your firm are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease.

As described in 21 C.F.R. § 310.544, any product that bears labeling claims that it "helps stop or reduce the cigarette urge," "helps stop or reduce smoking," or similar claims is a smoking deterrent drug product.<sup>8</sup> Products that are labeled, represented, or promoted as smoking deterrents, such as the RUYAN products marketed by your firm, are regarded as "new drugs" under section 201(p) of the Act (21 U.S.C. § 321(p)) because there is a lack of adequate data establishing that they are generally recognized as safe and effective for such use. See 21 C.F.R. § 310.544. These products are also "new drugs" under the Act because we are not aware of any data establishing that the RUYAN products are generally recognized among scientific experts as safe and effective for the other drug uses described above and in the products' labeling. "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. § 355) to be legally marketed in the United States. None of the RUYAN products or any of their components marketed by your firm is so approved; therefore, marketing these products in the United States violates section 505 of the Act.

Please be aware that the FDA has issued a letter addressed to the Electronic Cigarette Association (ECA) which explains, in detail, how the electronic cigarette industry can begin the drug approval process. For your convenience, we have enclosed a copy of that letter and encourage you to follow through with the recommendations.

The violations cited in this letter are not intended to be an all-inclusive list of deficiencies regarding your products, nor are the arguments raised here regarding them exhaustive. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations of delivering nicotine. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the referenced violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please state what actions you will take to address products that you have already distributed. If another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Please direct your response to FDA's Electronic Cigarette Mailbox at [FDAElectronicCigaretteMailboxCDER@fda.hhs.gov](mailto:FDAElectronicCigaretteMailboxCDER@fda.hhs.gov) or (301) 796-3110.

Sincerely,  
/Michael M. Levy, Jr./  
Michael M. Levy, Jr., Esq.  
Director, Division of New Drugs and Labeling Compliance  
Office of Compliance  
Center for Drug Evaluation and Research

<sup>1</sup> The website for Ruyan Holdings Ltd. of Hong Kong, [www.ruyan.com.cn](http://www.ruyan.com.cn), directs potential customers in North America to Ruyan America, Inc., at [www.ruyanamerica.com](http://www.ruyanamerica.com). The website [www.ruyan.com.cn](http://www.ruyan.com.cn) also features a press release consisting of an article in the Los Angeles Times that discusses Ruyan America and how Ruyan is "planning a big push in the United States." In addition, the website [www.ruyan.com.cn](http://www.ruyan.com.cn) contains user manuals that state: "The maintenance and repair of this product must be conducted by RUYAN America." The [www.ruyanamerica.com](http://www.ruyanamerica.com) website includes statements such as, "Ruyan America, Inc. is a U.S.-based joint venture partner of Ruyan Holdings Ltd. of Hong Kong," which further demonstrates the close relationship between Ruyan America, Inc. and Ruyan Holdings Ltd. of Hong Kong. Thus, it is appropriate to include your joint venture partner's website in our review. Additionally, as of November 24, 2009, the website for Nathan & James Group LLC, [www.getruyanusa.com](http://www.getruyanusa.com), stated: "the Company executed a Distribution Agreement with Ruyan America to market and sell its Ruyan Nicotine Delivery Products"; therefore, we also included this website in our review.

<sup>2</sup> E.g., P. Taylor, *Agents Acting at the Neuromuscular Junction and Autonomic Ganglia*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 193, 193-218 (J.G. Hardman, L.E. Limbird & A.G. Gilman eds., 2001).

<sup>3</sup> WORLD HEALTH ORGANIZATION, ICD-10 INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES, 10TH REVISION (2nd ed. 2007).

<sup>4</sup> AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL -- TEXT REVISION 192 (2000).

<sup>5</sup> E.g., N.L. Benowitz, *Drug Therapy. Pharmacologic Aspects of Cigarette Smoking and Nicotine*, 319 NEW ENG. J. MED. 1318 (1988).

<sup>6</sup> *Supra* note 3.

<sup>7</sup> E.g. T.B. Baker, T.H. Brandon & L. Chassin, *Motivational Influences on Cigarette Smoking*, 55 ANN. REV. PSYCHOL. 463 (2004).

<sup>8</sup> We note that the determination as to whether e-cigarette products would be considered Rx or OTC will be made during the review of an NDA submission.

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### E-Cig Technology Inc.



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Silver Spring, MD 20993-0002

#### WARNING LETTER

September 8, 2010

Mr. Sihui (Sam) Han  
Cixi E-Cig Technology Inc, Ltd.  
E-Cig Technology Inc.  
7488 Celosia St.  
Las Vegas, NV 89113

Dear Mr. Han:

This letter concerns the E-Cig Technology brand of electronic cigarettes, cigars, and USB cigarettes, and the components thereof, that are marketed by your firm (collectively "E-Cig Technology products").

Based on our review of the products' labeling, including your Internet website for these products, ([www.e-cig.com](http://www.e-cig.com)), the E-Cig Technology electronic cigarettes, cigars, and USB cigarettes are constructed with a lithium ion rechargeable battery, a microprocessor, a heating element, and a cartridge that contains, or is intended to contain, various chemicals, including nicotine (in varying specified levels). Nicotine and/or other chemicals are intended to be volatilized when the user inhales through these electronic cigarette products. These electronic products do not contain tobacco leaf or stem. Each E-Cig Technology product is intended to heat air as it is drawn through it by the user. This heated air purportedly volatilizes the chemicals contained in the replaceable cartridge component of these products. The volatilized chemicals are then inhaled by the user.

The E-Cig Technology E-Liquid and Healthcare E-Liquid products, which may or may not contain nicotine, are intended and labeled for use with the electronic smoking products described above to fill depleted or empty cartridges that are components of these electronic smoking products. Additionally, E-Cig Technology offers the components of electronic cigarettes, cigars, and USB cigarettes such as cartridges, inhalers, cores, atomizers, E-Cigarillo lid, batteries, and chargers for sale.

E-Cig Technology also distributes various accessories for electronic cigarettes, cigars, and USB cigarettes, such as syringes with needles, plastic dropper bottles, and plastic bottles, which are intended and labeled to aid users of these electronic smoking products when transferring the E-Cig Technology E-liquid into depleted or empty cartridges of various brands/models of these products and/or into empty E-Cig Technology cartridges.

As presently labeled and promoted, these E-Cig Technology products violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). As described in more detail below, E-Cig Technology products are unapproved new drugs marketed in the United States in violation of section 505 of the Act (21 U.S.C. § 355), are misbranded under section 502 of the Act (21 U.S.C. § 352), and adulterated under section 501 of the Act (21 U.S.C. § 351).

Both the "drug" and "device" definitions in sections 201(g) and 201(h) of the Act (21 U.S.C. §§ 321(g) and (h)), encompass products intended either to affect the structure or function of the body or to cure, mitigate, treat, or prevent disease. Based on our review of the products and their associated labeling and promotional materials,

these products are drug-device combination products, with a drug primary mode of action.

Statements in labeling and promotional materials, including your Internet website at [www.e-cig.com](http://www.e-cig.com), that reflect the intended uses for the products you market, include, but are not limited to, the following:

#### Home

"Why choose E-Cig? . . . E-Cig can help you reduce or quit smoking habits."

#### Instruction Manuals

"E-Cigarillo Instruction Manual

"It can refresh the smokers and satisfy their smoking addiction, making them happy and relaxed, so as to relief [sic] the suffering of quitting smoking.

The essentially [sic] differences between the Electronic Cigarillo and the ordinary Cigarette are as follows: . . . 5. According to the smoke-quitting procedure, the target of quitting smoke can be reached non-painfully within a certain period of ime . . . Suitable User . . . The smokers who want [sic] to quit smoking. Painless smoking abstention can be realized gradually by decreasing nicotine content."

#### Consumer Testimonials

"Testimonials

I have published my recommendations in one of the largest newspapers in Israel and in many other forums I am a member of, and to all my closest friends who ordered and stopped smoking also. -- A. Rahamim

I have not had a real cigarette since Monday night . . . I feel this could be the first thing that really works to keep me off real cigarettes (have tried the gum, patch, zyban, etc . . .)." -- A. Bastarache"

"Read Reviews

James USA . . . I am extremely pleased with this product and I will be purchasing more cartridges to move from dangerous cigarettes to your safer invention.

Conrad CO . . . I LOVE your product and all my friends have ordered because I was able to quit smoking with your Ecig!"

#### Press

"Take Smoking To Next Level . . .

One product called E-Rimonabant promises to help users lose weight and combat their smoking addiction. This electronic cigarette produces vaporable Rimonabant, an anorectic anti-obesity drug. As an inverse agonist for the cannabinoid receptor CBI, Rimonabant helps reduce appetite by creating a full or satisfied feeling.

'Rimonabant also reduces those strong cravings for smokers, which may help users quit smoking completely or reduce their smoking dependency. E-Rimonabant has the same characteristics and effectiveness as the original Rimonabant', states Sam Han, owner of E-Cig Technology, Inc. Ltd.

Another innovative product that has recently come on the scene at E-Cig is called E-Cialis. This electronic cigarette helps improve sexual capacity for men who suffer with ED (erectile dysfunction). More than 50 percent of men between the ages of 40 and 70 years experience ED to some degree. E-Cialis provides a simple solution by enhancing sexual performance when smoking an electronic cigarette.

'E-Cialis produces vaporable Cialis, an ED medication which is currently marketed in pill form and is more effective and longer lasting than Viagra."

#### News & Announcement

"5 July 2009 - New Product E-Cialis has been released . . . we have developed this new Vaporizable Cialis which have [sic] the same characteristic and the same effectiveness as the original Cialis. Now you can treat your ED or pulmonary arterial hypertension and improve your sexual capacity by smoking.

8 July 2009 - New Product E-Rimonabant has been released . . . this new Vaporizable Rimonabant which have [sic] the same characteristic and the same effectiveness as the original Rimonabant. Now you can Loss [sic] Your Weight and Reduce Your Smoking Addiction! by smoking.

5 May 2008 - Healthcare Liquid released . . . Healthcare Liquid is available now. These new developed [sic] Electronic Smoking Healthcare Liquid products not only give you the same feeling as a tobacco cigar or cigarette without suffering any tar and carbon monoxide smoking damages, but also give you the personal health care for your body."

#### Product Page

"Electronic Smoking Liquid Vitamins are a great way to increase absorption [sic] into the blood stream and produce maximum efficacy. It will give you not only the same feeling as a tobacco cigar or cigarette without suffering any tar and carbon monoxide smoking damages, but also give you the highest possible bodily absorption, and keeps your immune system running in tip-top shape. . . You can use it with any brand and model of E-Cig products."

The above statements demonstrate that the E-Cig Technology products marketed by your firm are intended both to affect the structure or function of the body and to mitigate, treat, or prevent disease. See 21 C.F.R. § 201.128 (describing the meaning of "intended use"). In particular, these statements suggest that these products are intended for use as smoking deterrents or to reduce dependence on traditional tobacco products, and are also capable of delivering nicotine. The scientific and medical communities have determined that nicotine is a pharmacological agent,<sup>1</sup> that nicotine addiction is a disease,<sup>2</sup> and that nicotine withdrawal is itself a recognized medical condition.<sup>3</sup> It is well understood that people smoke for the pharmacologically rewarding effects of nicotine, such as alleviation of stress and negative mood, enhancement of thinking, and increased alertness.<sup>4</sup> For an addicted smoker, the body has adapted to nicotine, and abstinence produces withdrawal and craving.<sup>5</sup> As a result, people also smoke to avoid the negative effects of nicotine withdrawal, such as anxiety, difficulty concentrating, negative mood, increased appetite, insomnia, and irritability.<sup>6</sup> Therefore, the claims noted above demonstrate that the E-Cig Technology products are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease.

Furthermore, the E-Cig Technology products and their components, described above, are also intended both to affect the structure or function of the body (e.g., by providing various vitamins for inhalation to supplement the diet, helping people lose weight, improving sexual capacity, and improving the overall health of the user) and to mitigate, treat, or prevent disease (e.g., mitigate, treat, or prevent erectile dysfunction).

As described in 21 C.F.R. § 310.544, any product that bears labeling claims that it "helps stop or reduce the cigarette urge," "helps stop or reduce smoking," or similar claims is a smoking deterrent drug product.<sup>7</sup> Products that are labeled, represented, or promoted as smoking deterrents, such as the E-Cig Technology products marketed by your firm, are regarded as "new drugs" under section 201(p) of the Act (21 U.S.C. § 321(p)) because there is a lack of adequate data establishing that they are generally recognized as safe and effective for such use. See 21 C.F.R. § 310.544. These products are also "new drugs" under the Act because we are not aware of any data establishing that these E-Cig Technology products are generally recognized among scientific experts as safe and effective for the other drug uses described above and in the products' labeling. "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. § 355) to be legally marketed in the United States. None of the E-Cig Technology or any of their components marketed by your firm is so approved; therefore, marketing these products in the United States violates section 505 of the Act.

E-Cig Technology products are also misbranded under section 502(e)(1)(A)(ii) of the Act (21 U.S.C. § 352(e)(1)(A)(ii)) because their labeling fails to declare the quantity of each active ingredients for their Cialis, Rimonabant, and E-liquid products.

The E-Cig Technology products marketed by your firm are also misbranded under section 502 of the Act (21 U.S.C. § 352) because they are intended for use as smoking deterrents under 21 C.F.R. § 310.544 but are not covered by an approved new drug application. The E-Cig Technology products are further misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)) because they do not bear adequate directions for their intended drug uses, including smoking deterrence and treatment of erectile dysfunction. "Adequate directions for use" is defined in 21 C.F.R. § 201.5 as "directions under which the layman can use a drug safely and for the purposes for which it is intended."

FDA's Division of Pharmaceutical Analysis (DPA) evaluated multiple samples of your products and in a sample of the Vitamin C E-Liquid, we detected DEG. The presence of DEG in the Vitamin C E-liquid drug product suggests that DEG has been added to a component in this drug product. DEG is an unexpected contaminant in Vitamin C E-liquid, perhaps tracing to DEG contamination of one of the ingredients used to manufacture Vitamin C E-liquid. The amount of this adulterant our lab found in Vitamin C E-liquid is fivefold in excess of the USP upper limit for DEG in Propylene Glycol and Glycerin, which are currently listed on your website as possible product ingredients.<sup>8</sup> The USP monographs for Glycerin and Propylene Glycol have a DEG upper limit of 0.1% to prevent and detect DEG intentionally added as an adulterant. In certain instances outside the United States in which a drug manufacturer failed to detect DEG in an ingredient such as glycerin or propylene glycol, the health consequences from DEG poisoning have been serious and irreversible. According to section 801(a)(3) of the Act (21 U.S.C. § 381(a)(3)), an imported drug that appears to be adulterated shall be refused admission into the United States. It appears that the DEG contamination renders your product adulterated under section 501(a)(2)(B) of the Act (21 U.S.C. 351(a)(2)(B)) and may not be imported into this country.

In addition, testing by FDA's DPA revealed that several samples of your product were tested and revealed that the amount of active ingredient in the product did not correspond with that amount represented on the labeling. Specifically, the Rimonabant prefilled cartridges, the Rimonabant Healthcare E-Liquid, and the nicotine containing prefilled cartridges and E-Liquids did not contain the amount of active ingredients as represented on your labeling. The failure of your products to contain the amount of ingredients they purport to contain renders the products adulterated under section 501(c) of the Act. (21 U.S.C 351(c)).<sup>9</sup>

Testing by FDA's DPA also revealed that the Cialis prefilled cartridges and the Cialis Healthcare E-Liquid contained amino-tadalafil, not tadalafil, the reference listed drug in Cialis. The substitution of this ingredient renders the products adulterated under section 501(d) of the Act. (21 U.S.C 351(d)).

Please be aware that the FDA has issued a letter addressed to the Electronic Cigarette Association (ECA) which explains, in detail, how the electronic cigarette industry can begin the drug approval process. For your convenience, we have enclosed a copy of that letter and encourage you to follow through with the recommendations.

The violations cited in this letter are not intended to be an all-inclusive list of deficiencies regarding your products, nor are the arguments raised here regarding them exhaustive. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the referenced violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please state what actions you will take to address products that you have already distributed. If another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Please direct your response to FDA's Electronic Cigarette Mailbox at [FDAAElectronicCigaretteMailboxCDER@fda.hhs.gov](mailto:FDAAElectronicCigaretteMailboxCDER@fda.hhs.gov) (301) 796-3110.

Sincerely,

/S/

Michael M. Levy, Jr., Esq.  
 Director, Division of New Drugs and Labeling Compliance  
 Office of Compliance  
 Center for Drug Evaluation and Research

<sup>1</sup> E.g., P. Taylor, *Agents Acting at the Neuromuscular Junction and Autonomic Ganglia*, in Goodman & Gilman's *The Pharmacological Basis of Therapeutics* 193, 193-218 (J.G. Hardman, L.E. Limbird & A.G. Gilman eds., 2001).

<sup>2</sup> World Health Organization, *ICD-10 International Statistical Classification of Diseases, 10th Revision* (2nd ed. 2007).

<sup>3</sup> American Psychiatric Association, *Diagnostic and Statistical Manual – Text Revision* 192 (2000).

<sup>4</sup> E.g. *Pharmacologic Aspects of Cigarette Smoking and Nicotine*, 319 *New Eng. J. Med.* 1318 (1988), N.L. Benowitz, *Drug Therapy*.

<sup>5</sup> See World Health Organization, *supra* note 2.

<sup>6</sup> E.g. T.B. Baker, T.H. Brandon & L. Chassin, *Motivational Influences on Cigarette Smoking*, 55 *Ann. Rev. Psychol.* 463 (2004).

<sup>7</sup> We note that the determination as to whether e-cigarette products would be considered Rx or OTC will be made during the review of an NDA submission.

<sup>8</sup> The website provides a choice of either the "propylene glycol" or "vegetable glycerin" base for the Vitamin C E-liquid.

<sup>9</sup> The actual ingredient content found in the E-Liquids and prefilled cartridges were inconsistent in many cases with the amounts specified on the manufacturer's website. Also, there were several incidences in which we detected nicotine in products represented as nicotine-free.

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### Johnson Creek Enterprises, LLC 9/8/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Minneapolis District Office  
Central Region  
250 Marquette Avenue, Suite 600  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
FAX: (612) 334-4142

September 8, 2010

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 10-20**

Christian Berkey, CEO  
Johnson Creek Enterprises, LLC  
320 N. Watertown Street, Suite F  
Johnson Creek, Wisconsin 53038

Dear Mr. Berkey:

This letter concerns "Smoke Juice," which is manufactured by your firm, and cartridge replacement products marketed by your firm under the "Johnson Creek" name.

As discussed below and in your labeling, these products are intended for use with electronic smoking products that are popularly called electronic cigarettes (or e-cigarettes), cigars and pipes. The electronic smoking products are generally designed to look and feel like the conventional tobacco products (cigarettes, cigars, and pipes). They are typically constructed with a battery, a sensor, a vaporizer or atomizer, and a cartridge that contains various chemicals, often including nicotine at various specified levels. These electronic products do not contain tobacco leaf or stem. Air is heated by these products as it is drawn through them by the user. This heated air purportedly volatilizes the chemicals contained in the cartridge components of these products and produces a mist or vapor upon each inhalation by the user that resembles and tastes like the smoke produced by tobacco products. The volatilized chemicals are then inhaled by the user.

The labeling and promotional material for your products, which includes your Internet website ([www.johnsoncreeksmoke.com](http://www.johnsoncreeksmoke.com)), offers the Johnson Creek Original Smoke Juice products in twelve flavors, which are available in four different levels of nicotine (0 mg, 11 mg, 18 mg, 24 mg) and two different levels of propylene glycol (normal and reduced): "J.C. Original," "Black Cherry," "French Vanilla," "Chocolate Truffle," "Arctic Menthol," "Tennessee Cured," "Espresso," "Mint Chocolate," "Simply Strawberry," and "Summer Peach." There is a propylene glycol-free line of Johnson Creek Smoke Juice products in six flavors, which are available in three different levels of nicotine (0 mg, 11 mg, 18 mg): "Domestic," "Marcado," "Island," "Wisconsin Frost," "Swiss Dark," and "Valencia." Additionally, you offer "JC Bees" which are disposable packets of Smoke Juice that allow users to refill their cartridge and dispose of the empty packet. All of these products are collectively described in this document as "Johnson Creek Smoke Juice products."

The Johnson Creek cartridge replacements are offered in three different forms: the "e-cigarette mini cartridge (DSE901)," the "e-cigarette mini cartridge (DSE103)," and the "e-cigarette pen-style cartridge (DSE801)" collectively described in this document as "Johnson Creek empty cartridge products."

The Johnson Creek Smoke Juice products are intended and labeled for use with various brands of so-called electronic cigarettes, cigars, and pipes to fill depleted or empty cartridges that are components of these

electronic smoking products. The Johnson Creek empty cartridges are intended to replace the disposable cartridges that accompany various brands and models of electronic cigarettes.

Johnson Creek also distributes various accessories for electronic cigarettes, cigars, and pipes, such as 10 mL syringes without needle, flex-tip cartridge needles, plastic dropper bottles, needle-tipped travel droppers, small plastic funnels, and tweezers which are intended and labeled to aid users of these electronic smoking products when transferring the Johnson Creek Smoke Juice into depleted or empty cartridges of various brands/models of these products and/or into empty Johnson Creek cartridges.

As presently labeled and promoted, these Johnson Creek Smoke Juice products violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). As described in more detail below, Johnson Creek Smoke Juice products are unapproved new drugs marketed in the United States in violation of section 505 of the Act (21 U.S.C. § 355) and are misbranded under section 502 of the Act (21 U.S.C. § 352).

Both the "drug" and "device" definitions in sections 201(g) and 201(h) of the Act (21 U.S.C. §§ 321(g) and (h)) encompass products intended either to affect the structure or function of the body or to cure, mitigate, treat, or prevent disease. Based on our review of the Johnson Creek Smoke Juice products and their associated labeling and promotional materials, these products are drug-device combination products, with a drug primary mode of action. Statements in labeling and promotional materials, including your Internet website at [www.johnsoncreeksmokejuice.com](http://www.johnsoncreeksmokejuice.com), that reflect these intended uses for the products you market include, but are not limited to, the following:

[www.johnsoncreeksmokejuice.com](http://www.johnsoncreeksmokejuice.com)

"Applause ...

If I had to wait two weeks, most likely I would have been back on smoke within a few days and I don't ever want to go there again, with as good as I feel right now. Daniel L.

... I have been off tobacco cigarettes for a week. I have been using an NJOY. I just received my first of many orders from your company. Norman S."

"News from Johnson Creek ...

"Effect of an E-Cigarette on Cravings and Withdrawal, Acceptability and Nicotine Delivery: Randomised Cross-Over Trial" - The University of Auckland Faculty of Medical and Health Sciences ... Aim ... To measure the effects of the Ruyan e-cigarette (EC) on craving relief and withdrawal and explore its acceptability and pharmacokinetic properties in comparison to placebo EC (i.e. with cartridges containing no nicotine), Nicorette nicotine inhalator and factory made cigarettes ... Conclusion ... The EC shows promise as a device that might aid cessation."

Promotional materials [brochures]

"Welcome to E-Smoking! A beginner's guide to E-Smoking ...

E-Smoking vs. Cigarette Smoking ... To many who take up e-smoking, it completely takes over for regular cigarette smoking. In fact many report never picking up a cigarette again after starting to e-smoke ...

Why E-Smoke? ... Most people who smoke, do so because they enjoy the tactile, emotional and physical sensations. E-smoking provides pleasures similar to those commonly associated with traditional smoking ...

Nicotine ... Nicotine is an alkaloid found in certain plants, predominantly tobacco ... When absorbed in small amounts, whether from cigarettes, cigars or e-cigarettes, nicotine can cause stimulation, a feeling of relaxation, calmness, and alertness. The effects of nicotine can last from minutes to hours, Although addictive, nicotine is widely considered far less dangerous than the ingredients in regular cigarettes."

"Archive for the 'News' Category ...

Response to the FDA - Why Johnson Creek is Different ... There's no diethylene glycol, there's no tobacco, no known carcinogens ... Comments ... Rick Hageman ... July 31, 2009 at 12:05 pm ... I've tried to quit several times by many methods - always went back because nothing addressed the physical addiction to the act of smoking. I was miserable as a non smoker 'cause I constantly craved the act of smoking. I've successfully abandoned tobacco thanks to the e-cig and Johnson Creek.

A Letter From the Founder ... For the past six months, we've been working tirelessly creating a formula that actually produces more vapor, more throat hit ... yet also happens to use fewer ingredients and is 100% tobacco-free! ... Comments ... August 2, 2009 at 3:22 pm ... I smoked for 40 years and was unable to quit until I purchased my first e-cigarette. I have not had a tobacco cigarette for over 3 months, and I no longer have any desire to have one!"

The above statements demonstrate that the Johnson Creek Smoke Juice products marketed by your firm are intended both to affect the structure or function of the body and to mitigate, treat, or prevent disease. See 21 C.F.R. § 201.128 (describing the meaning of "intended use"). In particular, these statements suggest that these products are intended for use as smoking deterrents or to reduce dependence on traditional tobacco products, and are also capable of delivering nicotine. The scientific and medical communities have determined that nicotine is a pharmacological agent,<sup>1</sup> that nicotine addiction is a disease,<sup>2</sup> and that nicotine withdrawal is itself a recognized medical condition.<sup>3</sup> It is well understood that people smoke for the pharmacologically rewarding effects of nicotine, such as alleviation of stress and negative mood, enhancement of thinking, and increased alertness.<sup>4</sup> For an addicted smoker, the body has adapted to nicotine, and abstinence produces withdrawal and craving.<sup>5</sup> As a result, people also smoke to avoid the negative effects of nicotine withdrawal, such as anxiety, difficulty concentrating, negative mood, increased appetite, insomnia and irritability.<sup>6</sup> Therefore, the claims noted above demonstrate that the Johnson Creek Smoke Juice products are intended to affect the structure or function of the body and to mitigate, treat, or prevent disease.

As described in 21 C.F.R. § 310.544, any product that bears labeling claims that it "helps stop or reduce the cigarette urge," "helps stop or reduce smoking," or similar claims is a smoking deterrent drug product.<sup>7</sup> Products that are labeled, represented, or promoted as smoking deterrents, such as the Johnson Creek Smoke Juice products marketed by your firm, are regarded as "new drugs" under section 201(P) of the Act (21 U.S.C. § 321(P)) because there is a lack of adequate data establishing that they are generally recognized as safe and effective for such use. See 21 C.F.R. § 310.544. These products are also "new drugs" under the Act because

we are not aware of any data establishing that these Johnson Creek Smoke Juice products are generally recognized among scientific experts as safe and effective for the other drug uses described above and in the products' labeling. "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. § 355) to be legally marketed in the United States. None of the Johnson Creek Smoke Juice products or any of their components marketed by your firm are so approved; therefore, marketing these products in the United States violates section 505 of the Act.

The Johnson Creek Smoke Juice products marketed by your firm are also misbranded under section 502 of the Act (21 U.S.C. § 352) because they are intended for use as smoking deterrents under 21 C.F.R. § 310.544 but are not covered by an approved new drug application. The Johnson Creek Smoke Juice products are further misbranded under section 502(t)(1) of the Act (21 U.S.C. § 352(t)(1)) because they do not bear adequate directions for their intended drug uses, including smoking deterrence. "Adequate directions for use" is defined in 21 C.F.R. § 201.5 as "directions under which the layman can use a drug safely and for the purposes for which it is intended."

Additionally, during our September 1-25, 2009, inspection of your manufacturing facility, Johnson Creek Enterprises, LLC, located at 320 N. Watertown Street, Suite F, Johnson Creek, Wisconsin, investigator(s) from the FDA identified significant violations of Current Good Manufacturing Practice (cGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug product(s), as described above, to be adulterated within the meaning of section 501(a)(2)(B) of the Act (21 U.S.C. § 351 (a)(2)(B)) in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, cGMP. Specific violations observed during the inspection include, but are not limited, to the following:

#### **CGMP Violations**

Your firm has not established a quality control unit having the responsibility and authority to approve and reject all components, drug product containers, closure, in-process materials, packaging materials, labeling and drug products, and the authority to review production records to assure that no errors have occurred (21 C.F.R. § 211.22(a)). For example, your firm has not established a quality control unit. Personnel with quality control unit responsibility have not been designated.

1. Your firm does not test each batch of drug product to determine conformance with final specifications (21 C.F.R. § 211.165(a)). Specifically, your firm does not test each batch of drug product prior to release.
2. Your firm has not established written procedures designed to prevent microbiological contamination of drug products not required to be sterile (21 C.F.R. § 211.113(a)). For example, your firm has not set microbial limits for your firm's oral liquid drug products, nor have you demonstrated preservative effectiveness.
3. Your firm has not conducted specific identification testing when components are accepted based on the supplier's report of analysis (21 C.F.R. § 211.84(d)(2)). For example, your firm accepts a Certificate of Analysis (COA) from the supplier of components. However, your firm does not conduct identity testing on your components or appropriate verification of the supplier's test results.
4. Your firm does not have a written testing program designed to assess the stability characteristics of drug products in order to determine appropriate storage conditions and expiration dates (21 C.F.R. § 211.166(a)). For example, your firm does not have a stability testing program for your firm's components and finished drug products.
5. Your firm's drug products do not bear an expiration date determined by appropriate stability data to ensure they meet applicable standards of identity, strength, quality and purity at the time of use (21 C.F.R. § 211.137(a)). For example, your firm does not have the stability data to support expiration dating for these products.

Please be aware that the FDA has issued a letter addressed to the Electronic Cigarette Association (ECA) which explains in detail how the electronic cigarette industry can begin the drug approval process. For your convenience, we have enclosed a copy of that letter and encourage you to follow through with the recommendations.

The violations cited in this letter are not intended to be an all-inclusive list of deficiencies regarding your products, nor are the arguments raised here regarding them exhaustive. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

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Sincerely,

/s/

Gerald J. Berg  
Director  
Minneapolis District

- <sup>1</sup> E.g., P. Taylor, Agents Acting at the Neuromuscular Junction and Autonomic Ganglia, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 193, 193-218 (J.G. Hardman, L.E. Limbird & A.G. Gilman eds., 2001).
- <sup>2</sup> WORLD HEALTH ORGANIZATION, ICD-10 INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES, 10TH REVISION (2nd ed. 2007).
- <sup>3</sup> AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL -- TEXT REVISION 192 (2000).
- <sup>4</sup> E.g., N.L. Benowitz, Drug Therapy. Pharmacologic Aspects of Cigarette Smoking and Nicotine, 319 NEW ENG. J. MED. 1318 (1988)
- <sup>5</sup> See WORLD HEALTH ORGANIZATION, supra note 2.
- <sup>6</sup> E.g. T.B. Baker, T.H. Brandon & L. Chassin, Motivational Influences on Cigarette Smoking, 55 ANN. REV. PSYCHOL. 463 (2004).
- <sup>7</sup> We note that the determination as to whether e-cigarette products would be considered Rx or OTC will be made during the review of an NDA submission.

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